DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 28 2010

Re: Folotyn
Docket No.: FDA-2010-E-0030

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,028,071, filed by Southern Research Institute, Sloan-Kettering Institute for Cancer Research, and SRI International, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Folotyn (pralatrexate), the human drug product claimed by the patent.

The total length of the regulatory review period for Folotyn (pralatrexate) is 4,591 days. Of this time, 4,406 days occurred during the testing phase and 185 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 2, 1997.

   The applicant claims January 31, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 2, 1997, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: March 24, 2009.

   The applicant claims March 23, 2009, as the date the new drug application (NDA) for Folotyn (NDA 22-468) was initially submitted. However, FDA records indicate that NDA 22-468 was submitted on March 24, 2009.

3. The date the application was approved: September 24, 2009.

   FDA has verified the applicant's claim that NDA 22-468 was approved on September 24, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Marina Larson
Larson & Anderson, LLC
P.O. Box 4928
Dillon, CO 80435-4928